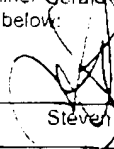


#19  
BP  
4-30-03

CERTIFICATE OF FACSIMILE TRANSMISSION 37 C.F.R. § 1.8	
I hereby certify that this correspondence is being transmitted to: Commissioner for Patents, Washington, D.C. 20231, Attn: Examiner Gerald G. Leffers, Jr., GAU 1636, facsimile number (703) 305-7939 on the date below:	
April 24, 2003 Date	 Steven L. Highlander

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

*In re* Application of:  
Val C. Sheffield et al.

Serial No.: 09/612,809

Filed: July 10, 2000

For: THERAPEUTICS AND DIAGNOSTICS  
FOR CONGENITAL HEART DISEASE  
BASED ON A NOVEL HUMAN  
TRANSCRIPTION FACTOR

Group Art Unit: 1642

Examiner: Unknown

Atty. Dkt. No.: IOWA:042USD1/SLH

**RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT  
APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID  
SEQUENCE DISCLOSURES DATED April 18, 2003**

U.S. Patent and Trademark Office  
Box Sequence, P.O. Box 2327  
Arlington, VA 22202

Commissioner:

This paper is submitted in response to the Notice to Comply with Requirements for  
Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures  
dated April 18, 2003, the deadline for response being May 18, 2003.

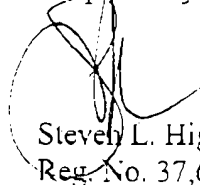
It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/IOWA:042USD1/SLH.

**RESPONSE TO NOTICE**

As explained to Examiner Leffers in a telephone call on April 23, 2003, the previously submitted Statement As Required Under 37 C.F.R. § 1.821(f) contained an explicit statement that no new matter was added by the sequences listing submitted on January 31, 2003 (attached). It is believed that the final page may have been lost, or the statement at the top of page 2 obscured.

Applicants believe that this paper fully responds to the Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures for this application.

Respectfully submitted,



Steven L. Highlander  
Reg. No. 37,642  
Patent Agent for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 474-5201  
(512) 536-4598 (facsimile)

Date: April 24, 2003

**Notice to Comply**

Application No.

09/612,809

Applicant(s)

SCHEFFIELD, ET AL

Examiner

Art Unit

Gerald G. Leffers Jr.

1636

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: the statement by Mr. Highlander that the sequence information provided by the specification and that present in the copies of the sequence listing provided in the papers submitted 2/4/03 is not sufficient in terms of a statement that no NEW MATTER is present in the submitted sequence listing (e.g. there are an additional 18 sequences present in the current listing as compared to the original listing, and the specification has been amended several times to date in prosecution). It would be remedial to submit a statement that clearly indicates that no new matter has been added with the documents submitted 2/4/03. The listings submitted 2/4/03 have been entered into the file. No new listings are needed.

**Applicant Must Provide:**

- ☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

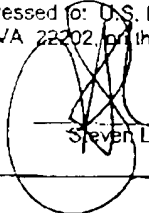
For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

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To Purchase PatentIn Software.....703-306-2600

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE**

CERTIFICATE OF MAILING 37 C.F.R. §1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: U.S. Patent And Trademark Office, Box Sequence Listing, P.O. Box 2327, Arlington, VA 22202, on the date below:	
January 30, 2003 Date of Deposit	 Steven L. Highlander

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE*In re* Application of:

Val C. Sheffield et al.

Serial No.: 09/612,809

Filed: July 10, 2000

For: THERAPEUTICS AND DIAGNOSTICS  
FOR CONGENITAL HEART DISEASE  
BASED ON A NOVEL HUMAN  
TRANSCRIPTION FACTOR

Group Art Unit: 1642

Examiner: Unknown

Atty. Dkt. No.: IOWA:042USD1/SLH

**RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT  
APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID  
SEQUENCE DISCLOSURES DATED DECEMBER 31, 2002**

U.S. Patent and Trademark Office  
Box Sequence, P.O. Box 2327  
Arlington, VA 22202

Commissioner:

This paper is submitted in response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures dated December 31, 2002, the deadline for response being January 31, 2003.

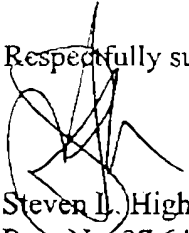
It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/IOWA:042USD1.

**RESPONSE TO NOTICE**

Submitted herewith is a Statement As Required Under 37 C.F.R. § 1.821(f); paper copy of sequence listing and computer readable form (CRF) which comply with requirements for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

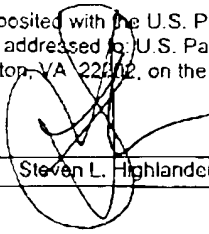
Applicants believe that the attached documents fully responds to the Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures for this application.

Respectfully submitted,

  
Steven L. Highlander  
Reg. No. 37,642  
Patent Agent for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 474-5201  
(512) 536-4598 (facsimile)

Date: January 30, 2003

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to U.S. Patent And Trademark Office, Box Sequence Listing, P.O. Box 2327, Arlington, VA 22202, on the date below:	
January 30, 2003 Date	 Steven L. Highlander

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Val C. Sheffield et al.

Group Art Unit: 1642

Serial No.: 09/612,809

Examiner: Unknown

Filed: July 10, 2000

Atty. Dkt. No.: IOWA:042USD1/SLH

For: THERAPEUTICS AND DIAGNOSTICS  
FOR CONGENITAL HEART DISEASE  
BASED ON A NOVEL HUMAN  
TRANSCRIPTION FACTOR

**STATEMENT AS REQUIRED UNDER 37 C.F.R. § 1.825(a) AND (b)**  
**AND STATEMENT AS REQUIRED UNDER 37 C.F.R. § 1.821(g)**

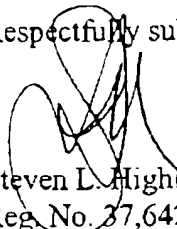
U.S. Patent and Trademark Office  
Box Sequence, P.O. Box 2327  
Arlington, VA 22202

Commissioner:

Submitted herewith is a substitute computer readable form and a substitute paper copy of the sequence listing of those sequences in the captioned patent application, wherein minor errors have been corrected. The substitute computer readable form of the sequence listing is the same as the substitute paper copy of the sequence listing. The sequence information provided in the Specification is also the same as the sequence listing of the enclosed substitute computer readable and paper forms of the sequence listing.

In accordance with 37 C.F.R. § 1.821(g), it is herewith represented that no new matter is included with this submission.

Respectfully submitted,



Steven L. Highlander  
Reg. No. 37,642  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 536-3184

Date: January 30, 2003

**Notice to Comply**

Application No.

09/612,809

Applicant(s)

SCHEFFIELD, ET AL

Examiner

Gerald G. Leffers Jr.

Art Unit

1636

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

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- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
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- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
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- ☐ 7. Other:

**Applicant Must Provide:**

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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